COVID-19 Vaccination Programme

Summary Plan for 2nd Booster Programme

14/04/2022

1. NIAC Guidance

On 5th April 2022, NIAC issued guidance (Appendix A) reiterating the importance of completing the primary and booster course even after an infection (in unvaccinated people) or a breakthrough infection post vaccination and recommending the administration of a second Booster to certain identified cohorts.

NIAC recommendations for the second Booster programme are:

- Delivered to the over 12 Immunocompromised and aged 65 and older population
- With an interval period of at least six months after the first booster was recommended although a minimum of 4 months can be used for operational reasons.
- Noting the post breakthrough infection interval of at least 6 months after the first booster or a minimum of 4 months which may be used for operational reasons (i.e. eligibility after COVID-19 infection)
- Comirnaty is to be used for those aged 12-29 years. Comirnaty/ Spikevax to be used for those aged 30 and older.
- If an mRNA vaccine is contraindicated or declined, consideration may be given to using a non mRNA vaccine as the second booster vaccine, following an individual benefit-risk assessment

2. CAG Guidance

The HSE's COVID-19 Vaccination Clinical Advisory Group (CAG) reconvened to provide guidance (Appendix B) on clinical issues pertaining to this NIAC Guidance. The CAG provided the following guidance:

- **Clinical Issue: Advice re interval between doses and post infection (4 or 6 months)** - it was agreed by CAG that it would be reasonable that the interval between first and second booster or post infection and second booster should be a minimum of 4 months.
- **Clinical Issue: Advice re definitions of "COVID infection" with regards to deferral of vaccination** - It was agreed by CAG that the definition should include COVID infection confirmed by PCR or antigen test, as self-reported by the patient.
- **Clinical Issue: Advice re immunocompromised definitions and pathway for review due to those immunocompromised at first booster being included** - It was agreed by CAG to proceed with table of only immunocompromised conditions taken from NIAC Chapter 5 as a guideline as this would support clinical judgement.

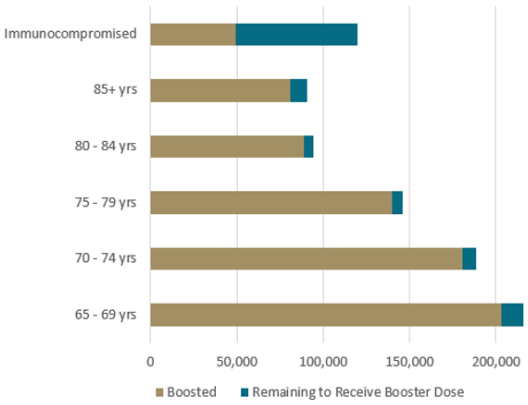
3. Key elements of 2nd Booster Plan

To operationalise this NIAC guidance and subsequent CAG guidance, the Vaccination Programme's Integrated Planning process developed a plan that was considered and accepted by the 13 April Vaccination Programme Working Group. Key elements of this programme are:

a. **Cohort Eligibility & Population -** In scope population (i.e. over 65 year olds and over 12 year olds Immunocompromised) is broken down in the table below by age group. Note that Immunocompromised population is to be confirmed following identification of any new immunocompromised.

65+ and Immunocompromised Cohort Sizes

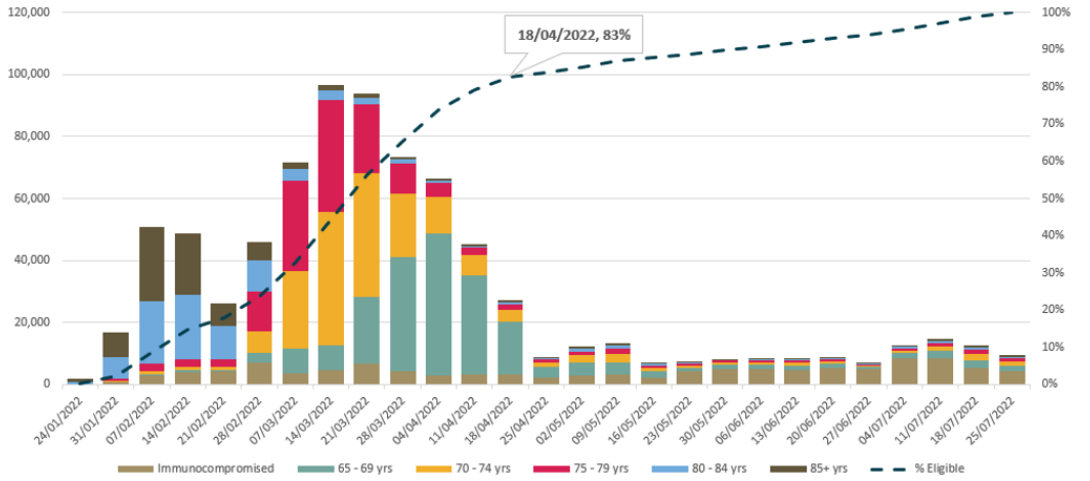
Cohort	(A) Fully Vaccinated	(B) Boosted	Remaining to Receive Booster Dose (A – B)
65 - 69 yrs	215,595	203,045	12,550
70 - 74 yrs	188,491	180,271	8,220
75 - 79 yrs	145,867	139,596	6,271
80 - 84 yrs	94,379	89,068	5,311
85+ yrs	90,446	81,042	9,404
IC	119,804*	49,401	70,403
Total	854,582	742,423	112,159



*Fully Vaccinated for Immunocompromised cohort is calculated based on the total who received an 'Immunocompromised' 3rd Dose

The expected eligibility profile for the 2nd Booster programme based on 4 months post date of vaccination or COVID infection is shown in the table below. Note that the majority of those becoming eligible from end May are Immunocompromised.

65+ and Immunocompromised Eligibility – 4 Months Post Additional Dose Date – Including Covid Cases



The above graph shows the eligibility profile for the 65+ and Immunocompromised cohorts based on 4 months post date of additional dose/ immunocompromised dose or date of Covid infection (whichever is later)

b. **Vaccine Administration Locations - An all channel approach will be adopted** meaning that all individuals within the >65 age group can be vaccinated through all vaccine administration channels (CVCs, GPs & Pharmacies). **GPs will focus on >70s but all in scope will be accepted** through all channels (GP, Pharmacies and CVCs).

c. **Vaccine Type and interval -** Those aged **12-29 years will receive Comirnaty**. Those aged **30 years and older can receive Comirnaty or Spikevax**. **Spikevax will be the preferred vaccine** to ensure utilisation and minimise vaccine expiry as far as possible. A second booster vaccination can be given after a **4 month interval from previous vaccination or COVID positive case**

d. **Start Date - HSE Channels (Vaccination Centres, Mobile Vaccination Teams and Hospital based teams) and GPs will begin administration from 22 April**. Participating **Pharmacies will begin administration from 28 April** (this later date is driven by required enabling ICT work). Pharmacies can continue to vaccinate 12-15 year olds in the intervening period.

e. **End Date - The target is for substantial completion of the in scope population by the beginning of June**. This target end date will support the implementation of the sustainable operating model and the alignment of **any Autumn COVID-19 vaccination programme with**

the Flu programme. There will be capacity in place in some vaccination centres and pharmacies over the summer months to support any "mop up" of the second Boosters required.

f. **Immunocompromised Plan -** Clinical guidance for identification of new Immunocompromised will be distributed to **Hospital Groups and GPs** who **will commence the identification and collation of population data**. In parallel, the **original immunocompromised cohort will start to receive text messages and be called for vaccination in line with their eligibility** (expected early May). The ICT requirements to enable a second Booster for immunocompromised will be delivered the week of 9th May. Following this the second booster programme for this cohort will commence.

4. Key enablers for rollout of second booster programme

a. **ICT -** Covax sprint 20 went live on 12-Apr enabling Booster 2s in GPs and CVCs. Pharmavax system changes to enable Booster 2 administration through Pharmacies will go live on 28 April. **Covax sprint 21 will go live in early May enabling Immunocompromised administration** (in line with their eligibility profile) and completing remaining changes required for Booster 2**.**

b. **Workforce -** VC workforce & GP/ pharmacy support confirmed. **Training and communications regarding ICT updates to be release in advance of 22 April commencement**

c. **Supply -** Update on GP portal with respect to ordering process to be in place prior to 22 April commencement

d. **Communications - Communications plan and key messages to be finalised** now that key elements of the plan have been agreed

5. Risks associated with Rollout

a. **Clarity of Messages -** Ongoing Primary & Booster programmes make the communication of clear messages to target populations challenging.

b. **Communication of Staggered Approach** - Initial administration will be through VCs & GPs (22 April) followed by Pharmacies (from 28 April).

c. **Communication of Immunocompromised Start** - Immunocompromised will begin early May with the date driven by collation of population data, further ICT changes and expected eligibility profile

d. **Continuing risk of low uptake** - Substantial completion of the 2nd Booster programme will be dependent on uptake which has been low since Jan despite a substantial group of people remaining eligible but not Boosted. Low or slow uptake for the 2nd Booster programme will potentially impact the target completion date of beginning Jun, the stock expiry issue and alignment with the Autumn flu programme

e. **Complexity of enabling ICT changes** - The complexity of ICT changes required to enable the administration through Pharmacies and Immunocompromised is such that there is

- a potential for the Pharmacy date of 28 April to be delayed
- significant risk of the Immunocompromised date of early May to be delayed

6. Appendix A - NIAC Guidance (05.04.2022)

RECOMMENDATIONS

These recommendations are made recognising the uncertainties regarding the trajectory of SARS-CoV-2 infections and on a precautionary basis to protect those most at risk of a severe outcome. They are based on current evidence and will be reviewed when more information becomes available. See the prior recommendations for primary and first booster vaccination.

1. Efforts to increase primary and first booster vaccination uptake should remain a public health priority. mRNA vaccines (Comirnaty and Spikevax) are the preferred vaccines for use in Ireland. • Those aged 12 years and older, including those pregnant or breastfeeding, should complete a primary course and receive a booster vaccine (total of three doses)
   • Those aged 5-11 years should complete a primary course (total of two doses) • Those with immunocompromise associated with a sub optimal response to vaccines at the time of their primary or booster vaccination:
      a) aged 12 years and older should complete a primary course, an additional dose and a booster vaccine (total of four doses)
      b) aged 5-11 years should complete a primary course and an additional dose (total of three vaccine doses)
2. Those who have a contraindication to or who decline a primary course or booster dose of an mRNA vaccine should be offered a non-mRNA vaccine.
3. Those who have had previous SARS-CoV-2 infection should complete their primary and booster vaccination to optimise their protection.

Second Booster Vaccine

1. To maintain high levels of immunity in those most at risk of severe disease, a second booster dose of an mRNA vaccine is recommended for the following:
   a) those aged 65 years and older
   b) those aged 12 years and older with immunocompromise associated with a sub optimal response to vaccines
2. The second booster vaccine is recommended at least six months after the first booster. A minimum interval of four months may be used for operational reasons.
   a) For those aged 12-29 years, Comirnaty (0.3ml/30 micrograms) should be given b) For those aged 30 years and older, Comirnaty (0.3ml/30 micrograms) or Spikevax (0.25ml/50 micrograms) should be given
3. For those who have had a breakthrough infection following a first booster vaccine, it is recommended to defer the second booster vaccine for six months following infection onset. A minimum interval of four months may be used for operational reasons.
4. If an mRNA vaccine is contraindicated or declined, consideration may be given to using a non mRNA vaccine as the second booster vaccine, following an individual benefit-risk assessment.

7. Appendix B - CAG Clinical Guidance on NIAC Guidance (08.04.2022)

Clinical Issue: Advice re interval between doses and post infection (4 or 6 months)

Clinical Advice: it was agreed by CAG that it would be reasonable that the interval between first and second booster or post infection and second booster should be minimum of 4 months. It was noted that this would support operational issues and align with planning and delivery of the flu campaign with COVID-19 vaccines in the Autunm.

Clinical Issue: Advice re definitions of "COVID infection" with regards to deferral of vaccination

Clinical Advice: It was agreed by CAG that the definition should include COVID infection confirmed by PCR or antigen test, as self-reported by the patient.
It is acknowledged that a key challenge is those who self-reported cases of infection cannot be linked to COVAX and that a separate forum is developing future testing criteria guidance, but it is expected that this guidance should not affect vaccination guidance for immunocompromised.

Clinical Issue: Advice re immunocompromised definitions and pathway for review due to those immunocompromised at first booster being included

Clinical Advice: It was agreed by CAG to proceed with table of only immunocompromised conditions taken from NIAC Chapter 5 as a guideline as this would support clinical judgement. This is set out in the appendix. The referral process should be made as easy as possible for new patients and vaccine should be available in all VAL's to support uptake.
Although outside the scope of this group, it was noted that a single clinical guidance on immunocompromised definitions would be beneficial for COVID-19 vaccination and administration of paxlovid. The CAG acknowledged that Liver and Neurology are included in paxlovid guidance but not included in NIAC guidance so not included in table (5a.2).

8. Appendix C - Supporting Data

65+ and Immunocompromised Cohort Sizes

Cohort	(A) Fully Vaccinated	(B) Boosted	Remaining to Receive Booster Dose (A – B)
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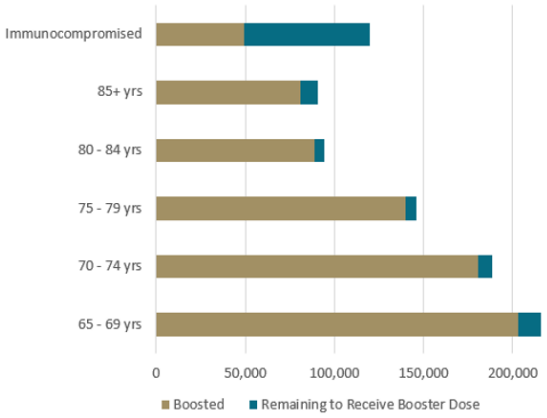

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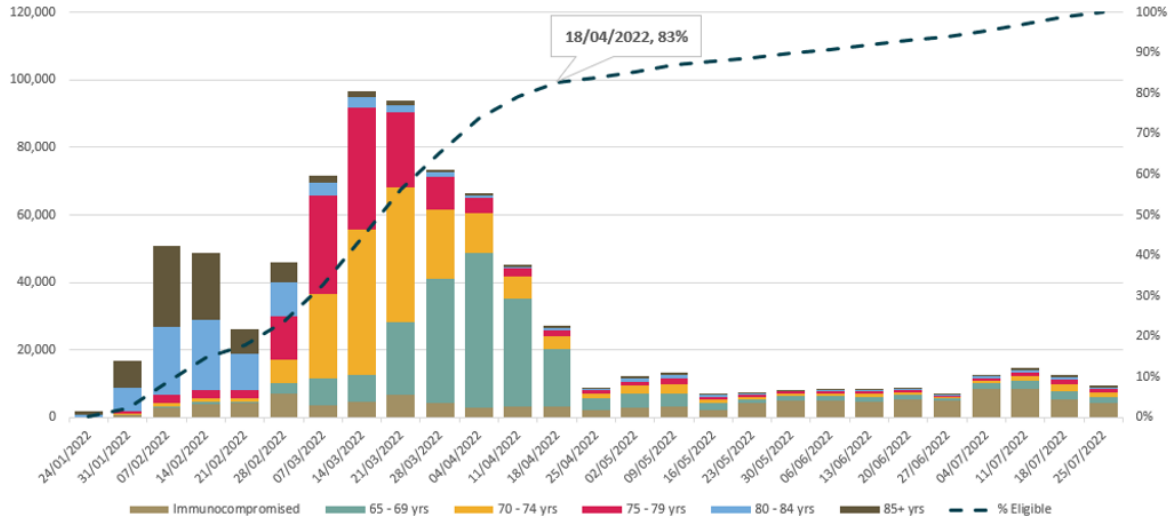
65+ and Immunocompromised Eligibility – 4 Months Post Additional Dose Date – Including Covid Cases



The above graph shows the eligibility profile for the 65+ and Immunocompromised cohorts based on 4 months post date of additional dose/ immunocompromised dose or date of Covid infection (whichever is later)

Immunocompromised Eligibility

An analysis was done to determine when immunocompromised people will become eligible to receive their first and second booster:

- Eligible for Booster 1: Those who received an immunocompromised dose but not a booster dose. The eligibility date of this group was calculated as the later date between 3 months after their immunocompromised dose or 3 months after their Covid positive test result.
- Eligible for Booster 2: Those who received an immunocompromised dose and a booster dose. The eligibility date of this group was calculated as the later date between 4 months after their booster dose or 4 months after their Covid positive test result